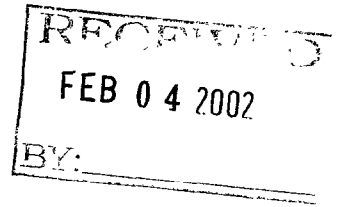




Scarangelo Company
1980 West 4th Street, Brooklyn, New York 11223
Phone: 718-998-8631 Fax 718-627-3656
Email-scarangelo2000@yahoo.com



November 13, 2001

Center For Food
Safety For Specified Nutrition FDA
200 C Street Southwest
Washington D.C. 20204

Re: Substantiation of claims

Dear Doctor Moore,

As per the requirements of the law I'm submitting the following statement for your records.

I, the undersigned, hereby certify that the claims that are subject of this notification are truthful and not misleading, and that the firm, Scarangelo Company, is in possession of substantiation of these claims.

I may be contacted by means of any of the above if further correspondence is required.

Very Truly Yours,

Gina Molinari
Scarangelo Company, President

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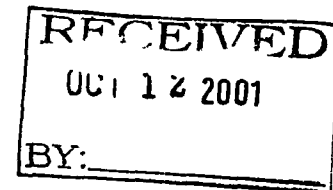


78131

Scarangelo Company
1980 West 4th Street, Brooklyn, New York 11223
Phone: 718-998-8631 Fax 718-627-3656
Email-scarangelo2000@yahoo.com

October 8, 2001

Center For Food
Safety For Specified Nutrition FDA
200 C Street Southwest
Washington D.C. 20204



Re: 30 Day Notification Law 21 CFR 101-93

Dear Doctor Moore,

I'm in the final stages of an importing project that I've been working on for quite some time. I understand that one of the final steps is to send 30 Day Notification to your office for **review** in order to satisfy regulations as outlined in 21 CFR 101-93.

Currently I'm seeking to import a collection of traditional herbal teas from Italy called **Tisana** (an Italian pun literally translated "healthy tea"). The collection consists of an assortment of 10 Tisane simply labeled as Healthy Teas numbered 1 through 10 followed by its descriptive name along with structure function claims. I will be marketing these as Dietary Supplements.

Great thought has been given to this project in order to remain within the restrictions of **the law** and to continue to do so as my business grows. Currently I've enclosed for your review **a copy of** the front and back labels along with their corresponding "Supplemental Facts" labels. **At this** time there is *web site*, only the tea labels and brochure. When we are ready to produce the website, it will state *exactly* what appears on the labels enclosed with respects to **structure function claims**, nothing more nothing less!

Upon the completion of your review and approval of the statements that have been made I will send these materials to be printed. If corrections are necessary please let me know so that I may make the necessary adjustments.

I may be contacted by means of any of the above if further correspondence is required.

Very Truly Yours,

Gina Molinari
Scarangelo Company, President

**COLLEZIONE
TISANE**

DIETARY SUPPLEMENTS

HEALTHY TEA COLLECTION

- NO. 1 Liv-A Klenz Tisana Bend
- NO. 2 Colon Klenz Tisana Bend
- NO. 3 Stress Relief Tisana Bend
- NO. 4 Slimming Tisana Blend
- NO. 5 Bloat Redux
Tisana Blend
- NO. 6 Promo Gest Tisana Blend
- NO. 7 Energizing Tisana Blend
- NO. 8 Celluloss Tisana Blend
- NO. 9 Respiratory Support
Tisana Blend
- NO. 10 Gas Relief Tisana Blend

WARNING

These statements have not been evaluated by the FDA. If pregnant or nursing seek advice of a health professional before using. This product is not intended to treat, cure or prevent any disease.

"Il Laboratorio dell'Erborista" was established in February 1984 in Pitigliano. This small town was chosen because of its richness in medicinal plants; about 80% of the medicinal plants of the Mediterranean grow wild in its environments.

The firm consist of two partners, Costanza Giunti & Fiorella Campana. Costanza studied Natural Sciences at the University of Siena and graduated as an herbalist in 1982. She arrived in Pitigliano looking for an untouched place where she could start her activity. She met Fiorella Campana in 1982 and after a year, Fiorella devoted herself completely to the laboratory.

Their activity has grown step by step; the first production, prepared with love, had handwritten labels and corks. As their philosophy of treating people's diseases with plants picked up, they became more and more renowned.

In 2001 Scarangelo Company brought these authentic blends to the United States, so that you can enjoy what the Italians have for almost the past two decades.

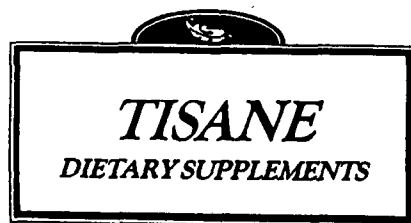
SALUTE!

Scarangelo Co.
1980 West 4th Street
Brooklyn, NY 11223
Phone: 718-998-8631
Fax: 718-627-3656



**il Laboratorio
dell'Erborista**

**LE TISANE DEL
LABORATORIO**



HEALTHY TEA NO. 1 LIVA- KLENZ TISANA BLEND

This special blend of herbs include artichoke, European ash-tree extract, mint and liquorice to support liver

Functions.

HEALTHY TEA NO. 2 COLON KLENZ

This special blend of herbs contain althea, cascara sagrada, and liquorice to help maintain regularity.

HEALTHY TEA NO. 3 STRESS RELIEF

This special blend of herbs exploits the properties of herbs such as passion-flower, hawthorn and chamomile to carry out a soothing and relaxing action.

HEALTHY TEA NO. 4 SLIMMING BLEND

Supporting metabolic function, this tisana blend incorporates the combined effect of fucus, anis, and liquorice. May be used as supplemental support as part of your weight loss program.

HEALTHY TEA NO. 5 BLOAT REDUX

A dietary supplement formulated to support the urinary system. This tisana incorporates the effective blend of exotic herbs including uva ursi, liquorice, equisetum, fennel and birch.

HEALTHY TEA NO. 6 PROMO GEST

This refreshingly delicious blend of herbs contains rhubarb, mint and liquorice. Effective especially after a meal to help promote digestion.

HEALTHY TEA NO. 7 ENERGIZING

Prepared with bitter orange, cinnamon and liquorice this blend provides vitality to the whole body.

HEALTHY TEA NO. 8 CELLULOSS

Thanks to the combined action of birch, equisetum, fucus, anis, and vervain this blend provides supplemental support for the circulatory system.

HEALTHY TEA NO. 9 RESPIRATORY SUPPORT

An herbal blend providing supplemental support for the respiratory system. This tisana blend incorporates the robust flavors of pine, elecampane and liquorice to create a refreshing effect

HEALTHY TEA NO. 10 GAS RELIEF

A special blend of herbs including anise, liquorice, mint and fennel to assist in the relief of gas and bloating. Containing the finest aromatic herbs including mint and anise you can enjoy the distinct flavor of this tisana unsweetened.

For generations Italians have enjoyed the tradition of drinking tisana, or healthy tea, beverage.

Until now this has remained their secret.

We at Scarangello Company are sure that you will enjoy the robust flavor, 'perfumed' aroma, and the unique texture of these authentic tisana blends as much as we do!

RECOMMEND: Approximately 2 Tbs. of herbs in two cups of water. Boil 2 min. Cover and let steep for 30 min. Filter and drink after a meal. May be diluted.

INGREDIENTS: artichoke, European ash-tree leaves, mint, and liquorice.
Not chemically treated.

WARNING:

The statements made on this package have not been evaluated by the FDA. If pregnant or nursing, seek advice of a health professional before using. This product is not intended to treat, cure or prevent any disease.

Distributed by

Scarangelo Co.

1980 West 4th Street, Brooklyn, NY 11223

Phone: 718-998-8631

Fax: 718-998-8691



Made in Italy

Net Wt. 3.75 OZ (100g)



**il Laboratorio
dell'Erborista**

HEALTHY TEA N. 1

Liv-A Klenn Tisana Blend
Dietary Supplement

An herbal dietary supplement formulated to support liver functions. This special blend includes artichoke, European ash-tree leaves, and liquorice.

Makes 7 to 11 servings

Tea N2

Supplement Facts

Serving Size 1 Tablespoon
Servings per container 7-11

| Amount per tablespoon | % Daily Value |
|---|---------------|
| Dietary Blend 10,000 mg | * |
| Althea Root/Marshmallow (Althaea Officinalis) | |
| Cascara Sagrada Bark (Rhamnus Purshiana) | |
| Liquorice Root (Glycyrrhiza Glabra) | |
| *Daily Value not established | |

Tea N. 1

Supplement Facts

Serving Size 1 Tablespoon
Servings per container 7-11

Amount per tablespoon

Proprietary Blend 5,000 mg

Artichoke Leaves (Cynara Scolymus)

European Ash Leaves (Fraxinus Excelsior)

Mint leaves (Mentha Arvensis)

Liquorice Root (Glycyrrhiza Glabra)

*Daily Value not established



**il Laboratorio
dell'Erborista**

HEALTHY TEA N. 2

Colon Klenn Tisana Blend
Dietary Supplement

Especially formulated to help maintain regularity, this special blend of herbs contains althea, cascara sagrada, and liquorice.

Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)

RECOMMEND: 1 Tbs. of herbs per cup of water. Boil for 2 min. Cover and let steep for 30 min. Filter and drink before going to bed. Should not exceed 2 cups per day. May be diluted.

INGREDIENTS: althea, cascara sagrada, and liquorice.
Not chemically treated.

WARNING:

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Scarangelo Co.

1980 West 4th Street, Brooklyn, NY 11223

Phone: 718-998-8631

Fax: 718-998-8691



Made in Italy

RECOMMEND: 1 Tbs. of herbs per cup of water. Boil for 3 min.

Cover and let steep for 3 min.

Filter and drink 2 to 3 cups a day with one before bed time.

INGREDIENTS: passion-flower, hawthorn, and chamomile
Not chemically treated.

WARNING:

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If pregnant or nursing, seek advice of a health professional before using. This
product is not intended to treat, cure or prevent any disease.

Distributed by:

Scarangelo Co.

1980 West 4th Street, Brooklyn, NY 11223

Phone: 718-998-8631

Fax: 718-998-8691



Made in Italy

RELAXING ACTION

Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)

NO 4

Supplement Facts

Serving Size 1 Tablespoon
Servings per container 7-11

| Amount Per Tablespoon | % Daily Value |
|---------------------------------------|---------------|
| Proprietary Blend 10,000 mg | * |
| Fucus/Sea Kelp (Fucus Vesiculosus) | |
| Alder Buckthorn Bark (Frangula Alnus) | |
| Anis Fruit (Pimpinella Anisum) | |
| Liquorice Root (Glycyrrhiza Glabra) | |

*Daily Value not established

and relaxing action.

Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)

RECOMMEND: 1 Tbs. of herbs per cup of water. Boil for
5 min. Cover and let steep for 20 min. Filter
and drink 2 to 3 cups per day.

INGREDIENTS: fucus, black-aldertree, anis, and liquorice
Not chemically treated.

WARNING:

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If pregnant or nursing, seek advice of a health professional before using. This
product is not intended to treat, cure or prevent any disease.

Distributed by:

Scarangelo Co.

1980 West 4th Street, Brooklyn, NY 11223

Phone: 718-998-8631

Fax: 718-998-8691



Made in Italy

RELAXING ACTION



**il Laboratorio
dell'Erborista**

HEALTHY TEA N. 3

Stress Relief Tisana Blend

Dietary Supplement

This special blend of herbs exploits the properties
of herbs such as passion flower, hawthorn,
and chamomile to carry out a soothing
and relaxing action.

Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)

NO 3

Supplement Facts

Serving Size 1 Tablespoon
Servings per container 7-11

| Amount Per Tablespoon | % Daily Value |
|---|---------------|
| Proprietary Blend 3000 mg | * |
| Passion-flower Leaves (Passiflora Incarnata) | |
| Chamomile Flowers (Matricaria Recutita) | |
| Hawthorn Leaves and Flowers (Rhamnus Catharticus) | |

*Daily Value not established

and relaxing action.

Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)



**il Laboratorio
dell'Erborista**

HEALTHY TEA N. 4

Slimming Blend

Dietary Supplement

Supporting metabolic functions, this tisana blend
incorporates the combined effect of fucus, anis,
and liquorice. May be used as supplemental
support as part of your weight loss program.

Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)

RECOMMAND: 1 Tbs. of herbs per cup of water. Boil for 5 min.
Cover and let steep for 10 min. Filter and
drink 3 cups per day.

INGREDIENTS: uva ursina, liquorice, equisetum,
Fennel, bearberry, and birch
Not chemically treated.

WARNING:

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If pregnant or nursing, seek advice of a health professional before using. This
product is not intended to treat, cure or prevent any disease.

Distributed by:

Scarangelo Co.

1980 West 4th Street, Brooklyn, NY 11223

Fax: 718-998-8691

Phone: 718-998-8631



Made in Italy

equisetum, fennel, and birch.

Net Wt. 3.75 OZ (100g)

Supplement Facts

Serving Size 1 Tablespoon
Servings per container 7-11

| Amount Per Tablespoon | % Daily Value |
|---------------------------------------|---------------|
| Proprietary Blend 9,000 mg | * |
| Rhubarb Root (R. Rhabarum) | |
| Mint Leaves (Mentha Arvensis) | |
| Liquorice Root (Glycyrrhiza Glabra) | |
| Burdock Root (Arctium Lappa) | |
| Bitter Orange Peel (Citrus Aurantium) | |

*Daily Value not established

urinary system. **Supplement Fac** Incorporates the effective
blend of exotic herbs including uva ursi, liquorice,
equisetum, fennel, and birch.

RECOMMEND: 1 Tbs. of herbs per cup of water.
Boil for 4 min. Cover and let steep for 15 min.
Filter and drink after a meal.

INGREDIENTS: rhubarb, mint, liquorice,
burdock, and bitter orange
Not chemically treated.

WARNING:

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If pregnant or nursing, seek advice of a health professional before using. This
product is not intended to treat, cure or prevent any disease.

Distributed by:

Scarangelo Co.

1980 West 4th Street, Brooklyn, NY 11223

Phone: 718-998-8631

Fax: 718-998-8691



Made in Italy

to help promote digestion.

Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)



**il Laboratorio
dell'Erborista**

HEALTHY TEA N. 5

Bloat Redux Tisana Blend

Dietary Supplement

A dietary supplement formulated to support the
urinary system. This tisana incorporates the effective
blend of exotic herbs including uva ursi, liquorice,
equisetum, fennel, and birch.

Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)

Supplement Facts

Serving Size 1 Tablespoon
Servings per container 7-11

| Amount Per Tablespoon | % Daily Value |
|---|---------------|
| Proprietary Blend 7,000 mg | * |
| Uva Ursi Leaves (Arctostaphylos Uva-Ursi Spreng) | |
| Liquorice Root (Glycyrrhiza Glabra) | |
| Corn Horse-tail Branches /Equisetum (Equisetum Arvense) | |
| Fennel Fruit (Foeniculum Vulgare) | |
| Birch Leaves (Betula Pendula) | |

*Daily Value has not been established

Supplement incorporates the effective
blend of exotic herbs including uva ursi,
equisetum, fennel, and birch.



**il Laboratorio
dell'Erborista**

HEALTHY TEA N. 6

Promo Gest Tisana Blend

Dietary supplement

This refreshingly delicious blend of herbs contains
rhubarb, mint, and liquorice. You may enjoy it
either sweetened or unsweetened, especially
effective after a meal to help promote digestion.
Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)

RECOMMEND: 1 Tbs. of herbs per cup of water.
Boil for 3 min. Cover and let steep for 10 min.
Filter and drink in the morning and early afternoon.

INGREDIENTS: damiana, bitter orange,
cinnamon, and liquorice
Not chemically treated.

WARNING:

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If pregnant or nursing, seek advice of a health professional before using. This
product is not intended to treat, cure or prevent any disease.

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Scarangelo Co.

1980 West 4th Street, Brooklyn, NY 11223

Phone: 718-998-8631

Fax: 718-998-8691



Made in Italy

Net Wt. 3.75 OZ (100g)

NO 8

Supplement Facts

Serving Size 1 Tablespoon
Servings per container 7-11

| Amount Per Tablespoon | % Daily Value |
|--|---------------|
| Proprietary Blend 7,000 mg | * |
| Fucus/Sea Kelp (Fucus Vesiculosus) | |
| Equisetum/Corn Horse-tail Branches (Equisetum Arvense) | |
| Birch Leaves (Betula Pendula) | |
| Anis Fruit (Pimpinella Anisum) | |
| Vervain Leaves (Verbena Officinalis) | |

to provide refreshing vitality.

RECOMMEND: 1 Tbs. of herbs per cup of water. Boil for 4 min.
Cover and let steep for 15 min.
Filter and drink at least 1 hour apart from meals.

INGREDIENTS: fucus, equisetum, birch, anis, and vervain
Not chemically treated.

WARNING:

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product is not intended to treat, cure or prevent any disease.

Distributed by:

Scarangelo Co.

1980 West 4th Street, Brooklyn, NY 11223

Phone: 718-998-8631

Fax: 718-998-8691



Made in Italy

Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)



**il Laboratorio
dell'Erborista**

HEALTHY TEA N. 7

Energizing Tisana Blend
Dietary Supplement

This special blend of herbs is prepared with bitter
orange, cinnamon and liquorice
to provide refreshing vitality.

Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)

NO 7

Supplement Facts

Serving Size 1 Tablespoon
Servings per container 7-11

| Amount Per Tablespoon | % Daily Value |
|---------------------------------------|---------------|
| Proprietary Blend 10,000 mg | * |
| Damiana Leaves (Turnera Diffusa) | |
| Bitter Orange Peel (Citrus Aurantium) | |
| Cinnamon Bark (Cinnamomum Zeylanicum) | |
| Liquorice Root (Glycyrrhiza Glabra) | |

to provide refreshing vitality.



**il Laboratorio
dell'Erborista**

HEALTHY TEA N. 8

Cellulose Tisana Blend
Dietary Supplement

This tisana blend combines the action of birch,
equisetum, fucus, anis, and vervain to provide
supplemental support for the circulatory system.

Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)

• **RECOMMEND:** 1 rounded Tbs. of herbs per cup of water.
Boil for 5 min. Cover and let steep for 15 min.
Filter and drink 3 to 4 cups a day with honey. May be diluted.

• **INGREDIENTS:** elecampane, myrtle, butterbur,
Pine bud, and liquorice
Not chemically treated.

WARNING:

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Distributed by:

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1980 West 4th Street, Brooklyn, NY 11223

Phone: 718-998-8631

Fax: 718-998-8691



Made in Italy

LIQUORICE
Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)

NO 9

Supplement Facts

Serving Size 1 Tablespoon
Servings per container 7-11

| Amount Per Tablespoon | % Daily Value |
|---|---------------|
| Proprietary Blend 8,000 mg | * |
| Liquorice Root (Glycyrrhiza Glabra) | |
| Elecampane Root (Inula Helenium) | |
| Myrtle Leaves and Fruit (Myrtus Communis) | |
| Butterbur Leaves (Petasites Hybridus) | |
| Pine Bud (Pinus) | |

*Daily Value not established



**il Laboratorio
dell'Erborista**

HEALTHY TEA N. 9

Respiratory Support Tisana Blend
Dietary Supplement

An herbal blend providing supplemental support
for the respiratory system. This tisana blend
incorporates the robust flavors of pine, elecampane,
and liquorice to create a refreshing menthol effect.
Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)

NO. 10

Supplement Facts

Serving Size 1 Tablespoon
Servings per container 7-11

| Amount Per Tablespoon | % Daily Value |
|--------------------------------------|---------------|
| Proprietary Blend 10,000 mg | * |
| Anise (Pimpinella Anisum) | |
| Coriander Fruit (Coriandrum Sativum) | |
| Fennel Fruit (Foeniculum Vulgare) | |
| Mint Leaves (Mentha Arvensis) | |
| Liquorice Root (Glycyrrhiza Glabra) | |

*Daily Value not established

incorporates the robust flavors of pine, elecampane

RECOMMEND: 1 Tbs. of herbs per cup of water.
Boil for 3 min. Cover and let steep for 15 min.
Filter and drink after a meal

INGREDIENTS: anis, coriander, fennel, mint,
And liquorice
Not chemically treated.

WARNING:

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If pregnant or nursing, seek advice of a health professional before using. This
product is not intended to treat, cure or prevent any disease.

Distributed by:

Scarangelo Co.

1980 West 4th Street, Brooklyn, NY 11223

Phone: 718-998-8631

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Made in Italy



**il Laboratorio
dell'Erborista**

HEALTHY TEA N. 10

Gas Relief Tisana Blend
Dietary Supplement

Especially effective after a meal to relieve gas and
bloating. Containing the finest aromatic herbs
including mint and anise you can enjoy the distinct
flavor of this pleasant beverage either sweetened or
unsweetened.

Makes 7 to 11 servings

Net Wt. 3.75 OZ (100g)